



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al. )  
Serial No. 10/773,731 ) Group Art Unit: 2643  
Filed: February 5, 2004 ) Confirmation No. 8615  
For: HEARING AID SYSTEM )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Leon Hirsch declares and says that:

1. I am President of Vivatone Hearing Systems, LLC ("Vivatone"), and assignee of the above-referenced application. I have been intimately involved in the development, manufacture and sale of the open ear hearing aid system, which includes a behind the ear unit coupled to an open ear speaker within the ear canal since 2002.

2. The above-referenced application describes and claims an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal, which receiver has an architecture that provides what I generally refer to as an "open ear configuration". More specifically, the application describes and claims, in part:

a hearing aid system, comprising:

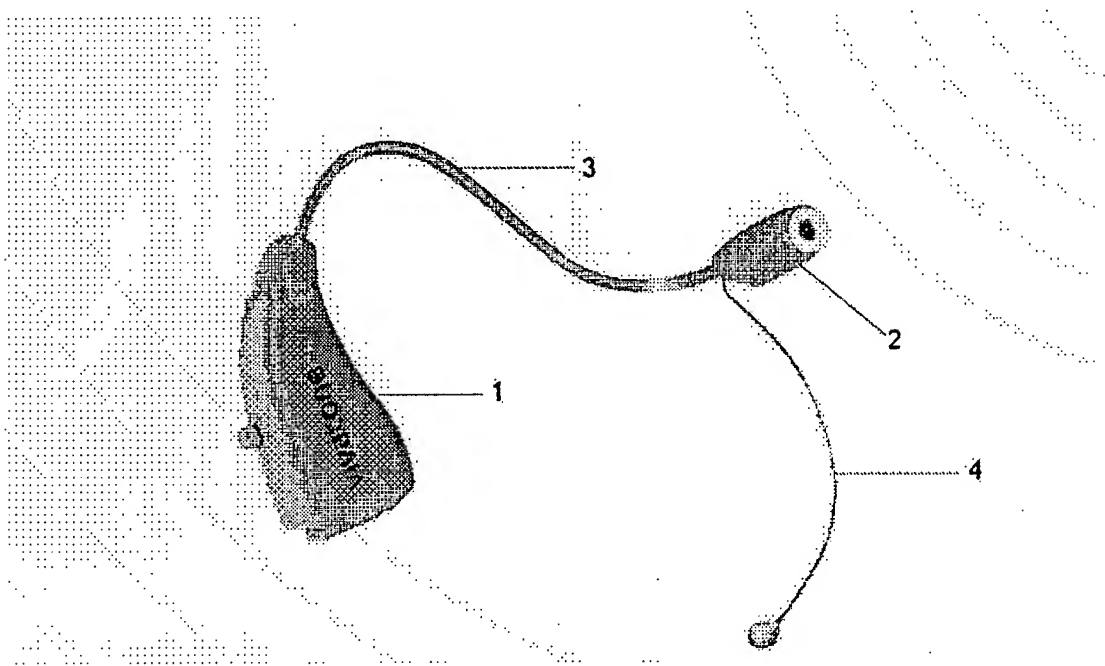
a microphone sampling position located externally of an ear canal of a user,

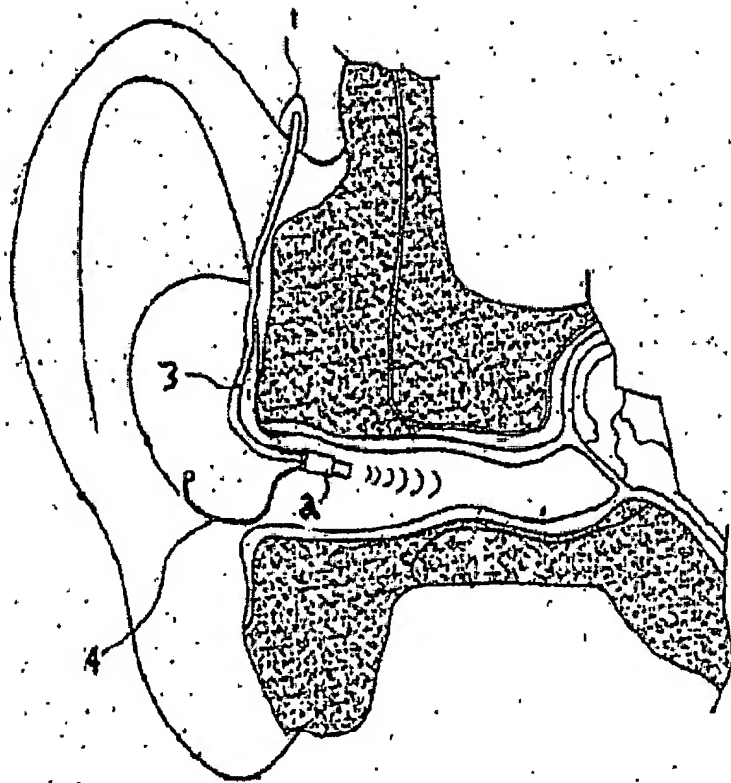
a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through

the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration, wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. As noted in my Declaration of October 31, 2006, the claims of the above-referenced claims correlate with the commercial Vivatone open ear hearing aid system. Reference is made to the following images of the commercial Vivatone device as an aid to review of the following claim chart:





The following claim chart relates aspects of the claimed Vivatone hearing aid to commercialized Vivatone hearing aid to which the above-described commercial success figures above relate. Relevant portions of independent claims (which portions are substantially reproduced in the remaining independent claims) are reproduced below:

A hearing aid, comprising: a microphone sampling position located externally of an ear canal of a user;	The Vivatone hearing aid includes a microphone and microphone port located within the behind-the-ear component (1).
a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal;	The receiver (2) comprises a speaker (5) provided within the ear canal in an open ear configuration and is suspended within the ear canal by virtue of the stiffness of the intermediate wire (3) and/or the effect of the concha wire (4).

wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;	The sampled sounds are passed to an amplifier provided in the behind the ear component (1), amplified in accordance with hearing loss programming and are relayed to the speaker (5) via the intermediate wire (3), which is provided around a portion of the external ear into the ear canal opening.
wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit	The microphone port and amplifier are both contained within the behind the ear component (1).

**The additional aspect of the independent claim 1 is also embodied in the commercial Vivatone device, including the receiver generating about three decibels or below of insertion loss over a portion of human ear audible frequencies.**

4. My open ear hearing aid was first commercially launched by Vivatone in the first quarter of 2004, and is embodied in a product designated the “Vivatone Mini”, the “Vivatone Standard” or the “Vivatone Dual”. At the time of the open ear hearing aid commercial launch, Vivatone, as a small startup company whose product line consisted solely of the open ear hearing aid product, did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivatone did not engage in any television or radio advertising, and only minimal other national advertising. National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal. Notwithstanding the lack of name recognition and advertising, Vivatone’s open ear hearing aid has achieved a high degree of commercial success. Sales were generated principally by word of mouth by audiologists, and by side-by-side demonstrations of Vivatone’s open ear hearing aid system with other hearing aids. As may be seen from the sales charts at Exhibit 1 of my September 13, 2006 Declaration, domestic unit sales and

domestic net revenues have steadily increased from the first quarter of 2004 until December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivatone's open ear hearing aid went from no sales to almost eighteen million dollars. Those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.<sup>1</sup>

5. Various types of hearing aids have been sold marketed and sold for more than 30 years, including completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids. The first three types (CIC, ITC and ITE) occlude the ear canal by providing electronics either within the ear canal or immediately adjacent to the ear canal (e.g., in the bowl of the ear). BTE hearing aids do not occlude the ear canal, but instead provide all components in a housing behind the ear and an open tube for directing sound to the ear canal from the speaker housed in the BTE. The Vivatone open ear hearing aid is the **FIRST** product in those 30 some odd years to incorporate a design that separates the amplification from the speaker, placing the amplification behind the ear (like a BTE device, but unlike the CIC, ITC and ITE devices) while at the same time suspending a small profile speaker in the ear canal to give an open ear configuration. Thus, it took the industry 30 some odd years to create Vivatone's novel open ear hearing aid system configuration, which system minimizes insertion loss and occlusion effect and uses the ear's natural "receiver" to the fullest, mixing natural sounds and amplified sounds in the ear for excellent sound clarity (see the Vivatone Hearing System's brochure at Exhibit 2 of my September 13, 2006 Declaration).

6. While various types of hearing aids have been known for decades, no other company in the hearing aid field was motivated to separate the microphone sampling and

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<sup>1</sup> However, since the introduction of the Oticon and Hansaton hearing aid products, which as discussed hereafter, constitute copies of our claimed invention, U.S. domestic sales of the Vivatone product have declined.

amplification from a suspended in-canal speaker (to provide an open ear fitting remote from the BTE microphone and amplifier) until the Vivatone open ear hearing aid in 2004. In my opinion, this fact alone indicates that it was not obvious to provide for such a novel open ear configuration in a hearing aid system.

7. Our open ear hearing aid system resolves the biggest problems that hearing aid wearers experienced prior to the introduction of the Vivatone hearing aid solution: occlusion, insertion loss, feedback and resonance effects (depending on the type of hearing aid used). Occlusion is the “head in the barrel” effect created when the hearing aid wearer speaks or chews. Feedback is the whistling sound experienced when a patient places a telephone near the ear or other structure. Feedback is similar to the whistling sometimes heard in an auditorium when the microphone is too close to the speaker. Further, BTE devices feeding sound to the ear canal via a sound tube suffer from resonance effects. Vivatone revolutionized hearing aids by developing a product that eliminates the *long felt need* with regard to each of these annoyances. That is, Vivatone enhances hearing while enabling the wearer to enjoy normal speaking, eating or telephone conversation without interference.

8. The reason that Vivatone hearing aids are able to provide these benefits is its unique design. Vivatone’s microphone and amplifier are housed in a small plastic case located behind the ear. Unlike other hearing aids, Vivatone delivers sound from the microphone port in the BTE electronically to its speaker in the open ear canal. The speaker is small enough to allow the ear canal to remain open, and therefore, is non-occluding. This revolutionary approach has advanced the acceptance of hearing aids significantly. As noted, prior to Vivatone, hearing aids either occluded the ear canal or transmitted sound from a speaker located behind the ear to the ear canal through a plastic tube. These designs cause either occlusion or insertion loss or distortion or lack of clarity. Vivatone’s open ear speaker allows the patient’s residual natural sound to combine with the enhanced hearing provided by Vivatone’s processor, giving crisp, clear sound to the patient.

9. I noted in my Declaration of September 13, 2006 that Oticon introduced the "Delta" hearing aid product in February, 2006 and that Hansaton announced the "Free Soundmanager" hearing aid in March, 2006. Both of these companies are direct competitors of Vivatone. These companies copied our open ear hearing aid invention and aggressively marketed and highlighted the benefits of our open ear hearing aid invention as being a significant advance in the hearing aid field.

10. I also noted in my Declaration of October 31, 2006 that on October 17, 2006, Siemens announced its own RIC ("Receiver in the Canal") hearing aid, called the "CENTRA Active", which is to be released in the beginning of 2007. This company also copied our open ear hearing aid invention and is aggressively marketing and highlighting the benefits of our open ear hearing aid invention as being a significant advance in the hearing aid field.

11. It has recently come to my attention that Oticon was recently selected as an International CES Best of Innovations 2007 Design and Engineering Award winner for its Delta product (which, as previously discussed, is a copy of the Vivatone's claimed invention). Exhibit 1, attached hereto, is a November 8 PRNewswire report, which characterizes the Delta as being a "new category." The report states, "Its revolutionary design is made possible by placing its receiver into the ear canal at the end of a thin, transparent sound wire." This report calls the Delta hearing aid (which copied our Vivatone hearing aid) "revolutionary" and emphasizes that the marketplace views the configuration as being new.

12. It has also recently come to my attention that a fourth Vivatone competitor, Interton Horgerate, GmbH, recently announced a new RITE (Receiver in the Ear) product, called Shape. Exhibit 2 illustrates the new Interton Shape product alongside the Oticon Delta, the Hansaton Free, the Siemens Centra Active, and our own Vivatone hearing aid. Vivatone's configuration is being copied over and over again by our major

competitors. Like the others, the Interton Shape includes the BTE component with hearing aid electronics, a receiver in the ear in an open ear fitting, and a thin wire connecting the open ear receiver to the rest of the electronics in the BTE.

13. The Interton advertising also continually characterizes its configuration (copied from Vivatone's configuration) as innovative and otherwise lauds the product. Exhibits 3-5 provides advertising literature for Interton's Shape hearing aid (just as the previously submitted Exhibits showed such literature for Oticon, Hansaton, and Siemens). Reference will be made to selections from Exhibits 3-5 immediately below:

Referring to Exhibit 3, the advertisement includes on its front page a large heading "**You will hear the difference**". Page 2 does the same, with an image of the product and images of a coat hanger turning into a cymbal. Page 3 goes on to indicate that the Shape is "**A new dimension in hearing comfort**". Page 4 overtly touts the configuration by stating:

**The secret of Shape – One solution, two units**

*With Shape, INTERTON is the first German company to place the receiver (speaker) in the ear canal while the sound processor is worn behind the ear. The result: a highly effective hearing system that provides a much richer sound experience.*

*The speaker is positioned in the ear canal. The speaker is positioned in the ear canal, while the sound processor sits behind the ear. The units are connected by an invisible tube. By placing the speaker in the ear canal, it is closer to the drum than traditional hearing aids. This unique configuration makes excellent sound quality and cosmetic discretion possible.*



**Shape – get all the advantages of in-the-ear solution (ITE’s) and behind-the-ear solution (BTE’s). *Because all advantages are combined, Shape offers many benefits. If you are an experienced hearing aid wearer, you are familiar with the advantages and disadvantages of different hearing aids.***

***With Shape, there are no compromises – the best of both types of hearing systems all in one device.***

Page 5 goes on to describe the open fitting:

***You will hear the difference – the whole world of sound***

***You will feel the difference – a new quality of life***

***Comfort and sound quality – the speaker is held in the ear by a soft dome...***

***Open for better perception – Since the ear is not plugged, your voice won’t sound odd to you. The sounds of chewing and swallowing won’t overwhelm your sense of hearing...***

***Enjoy the difference!***

Pages 8 and 9 show an image of “Shape in use” (as being virtually invisible) and detail the “Advantages of Shape at a glance”:

***Almost invisible – the transparent tube, together with the very small and inconspicuous housing, meets the highest aesthetic and discretion demands.***

***Superior sound quality – enjoy speech, music and the sounds of nature again.***

***A high level of wearing comfort – your ear is not plugged. Listening feels free and natural. The dome is soft and comfortable.***

**Minimization of feed back – *with Shape’s unique configuration unpleasant whistling is a thing of the past.***

**You will hear the difference**

Finally, page 10 shows the Shape configuration, which describes the interrelationship between the BTE, the tube and the external receiver unit.

Referring now to Exhibit 4, the front cover begins with a heading “**The best of both worlds...Shape**”. Page 2 shows an image of a BTE combining with a CIC to result in SHAPE. Page 3 describes the benefits of Shape:

**A new dimension in hearing comfort – Shape**

**The best of both worlds – *Shape has an external receiver which is located directly in the auditory canal. Shape therefore combines the advantages of smaller CIC hearing aid solutions with the high level of wearing comfort of open mini BTEs to form an efficient and comfortable product innovation.***

**Almost invisible – *Shape is an extremely small and light weight hearing aid system. Due to its broad fitting range, Shape achieves the highest degree of speech understanding and hearing comfort for a greater part of your customer base.***

**One solution, two units – *Shape’s receiver is placed in the auditory canal, providing the sound quality of a CIC. However, the digital signal processor and directional microphone system are positioned behind the ear – eliminating feedback and allowing for unprecedented level of discretion. There is no need to compromise one for the other – Shape offers the best of both worlds.***

***INTERTON is the first German company to offer you, in the form of Shape, a combination of excellent acoustic quality, open care, discretion, wearing comfort and durability.***

**Your customers will appreciate it.**

Page 4 opens with “The benefits to you – advantages for as far as the eye can see” and “*Shape provides you with an efficient solution – all the advantages of an open BTE and a CIC are combined without compromise.*” Page 4 goes on to highlight the advantages of the BTE (*open fitting, high degree of comfort, cosmetically attractive, etc.*) as well as some disadvantages (such as *loss of acoustic quality through thin tube*). Page 4 also lists advantages of the CIC (*excellent acoustic quality, invisible*) as well as disadvantages (*Occlusion, less amplification, limited power, Expenditure in terms of time due to manufacturing of the shell, etc.*).

Page 5 lists the advantages of Shape, with no disadvantages. With regard to the **external receiver unit**, these include:

- *A broad fitting range*
- *Extremely high performance in the high frequencies (important for understanding speech)*
- *Optimum utilization of the residual volume of the auditory canal*
- *No thin tube – a cable instead (no loss in the high frequencies and no stationary wave resonances)*
- *No mechanical feedback (the result: excellent acoustic quality and improved understanding of speech)*
- *Open fitting*
- *Silicone parachute sits comfortably in the ear*

With regard to the **cosmetic appearance and comfort**, benefits include:

- Cosmetically attractive
- Light as a feather and almost invisible
- High degree of comfort
- Easy to handle, care for and operate

Page 6 reiterates:

*Your customers will feel the difference – ... Shape is almost invisible and the ideal solution for customers who attach importance to an aesthetic appearance. Due to the open solution, former ITE users perceive their own voice much more naturally and benefit from increased comfort and an overall markedly improved quality of life.*

Referring now to the introduction to Interton's technical datasheet at Exhibit 5, the qualities of the claimed configurations are summarized in part by:

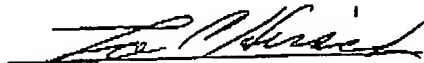
*Combining the advantages of BTE and ITE instruments, Shape brings the best wearing and listening comfort of both worlds to the customer. By having the receiver placed in the ear canal, it delivers excellent sound quality, a broad fitting range, and more gain. Shape is an occlusion free and invisible hearing solution with an attractive wearing style... No ear mould or shell is needed...*

*Shape is the most attractive, occlusion free and robust solution with the best sound quality and largest fitting range possible for open fittings. Altogether you will find that Shape is the direct route to better hearing. You will hear the difference.*

14. As is evident from the above, Interton (just as did Oticon, Hansaton and Siemens) not only copies the claimed configuration, but lauds the configuration as innovative. Interton overtly details the problems and disadvantages of prior BTE and CIC devices

and provides detail on how the RITE open fitting solution solves all of the prior problems and disadvantages.

I declare under penalty of perjury that the foregoing is true and correct.

  
Leon Hirsch

November 21, 2006

# **EXHIBIT 1**



## Hearing Device Oticon Delta Named 'Best of Innovations' at Prestigious CES Innovations 2007 Awards

NEW YORK, Nov. 8 /PRNewswire/ -- At the International CES press preview today, the American Consumer Electronics Association (CEA), producer of the world's largest consumer electronics show (CES), announced that Oticon, A/S has been selected as an International CES Best of Innovations 2007 Design and Engineering Award winner. The "Oscars" of the electronics world honored the company's revolutionary Oticon Delta hearing device with the Best of Innovations 2007 in the Personal Electronics Products category. One of the most widely renowned consumer technology awards programs worldwide, Innovations 2007 recognizes the best-designed and best-engineered products in consumer technology. Judges awarded Oticon Delta one of the highest scores in the Personal Electronics category based on its value to a user, aesthetics, contributions to quality of life, and innovative qualities.

"It isn't often that a hearing device competes with hundreds of cutting-edge consumer electronics products from leading international electronics companies and comes out on top," states Niels Jacobsen, President and CEO of Oticon and William Demant Holding. "We designed Delta to change the way people view hearing aids. This award proves that we've moved the concept of hearing aids into competition with some of the most desired electronic equipment in the world. It is an incredible affirmation of the success of our mission to motivate image-conscious people with hearing loss to consider Delta as a high-tech, attractive solution."

The groundbreaking design that characterizes Oticon Delta has set a new benchmark in hearing aid design, creating a whole new category of hearing solutions. Delta features a miniature triangular design with sleek lines, hot colors and a brushed metallic surface. Its revolutionary design is made possible by placing its receiver into the ear canal at the end of a thin, transparent sound wire. Combining the best of two worlds, Delta merges the cosmetic advantages of in-the-ear instruments with the technological possibilities of behind-the-ear devices. Invisible behind the ear, the innovative design houses state-of-the-art digital technology allowing unprecedented sound quality and boosting speech understanding even in the most difficult listening situations.

The Best of Innovations award is one of many accolades the trendy hearing device has earned since its introduction earlier this year. A distinguished panel of international jurors awarded Oticon Delta the Red Dot Award 2006, one of the most sought-after design awards worldwide, for its superior design quality and innovative design. In addition, Delta received the design award of the Federal Republic of Germany 2007.

This year's Best of Innovations 2007 awards are given to the most honored products in each of 31 product categories. Products entered in this prestigious program are judged by a preeminent panel of independent industrial designers, engineers and members of the trade press to honor outstanding design and engineering in state-of-the-art consumer electronics.

Oticon Delta will be highlighted and displayed numerous times during the 2007 International CES which runs January 8-11, 2007 in Las Vegas, Nevada. The Best of Innovations Showcase will be on display at Innovations

Plus at the Sands/Venetian which houses the hottest emerging technologies in the consumer electronics industry. Delta will also be showcased in the Grand Lobby of the Las Vegas Convention Center and at CES Unveiled: The Official Press Event of the International CES from 4-7 p.m. on Saturday, January 6, in the Marco Polo Ballroom at the Venetian.

About Oticon

Oticon is one of the most innovative hearing aid manufacturers on the market. With over 100 years of experience, Oticon looks back on a number of technological breakthroughs in hearing aid history that have made a significant difference for people with hearing loss. Oticon is the only hearing instrument manufacturer with its own research center ensuring that the needs of hearing aid users are always put first when developing new solutions.

For more information about Oticon Delta please visit <http://www.my-delta.co>  
<http://www.oticon.com>.

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